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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,970	08/06/2003	James A. Bianco	CELLTH 3.0-012	1243
530 7590 08/23/2007 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER TELLER, ROY R	
			ART UNIT 1654	PAPER NUMBER
			MAIL DATE 08/23/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/635,970

Applicant(s)

BIANCO, JAMES A.

Examiner

Roy Teller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

This office action is in response to the communication, received 4/9/07.

The finality of the previous office action is withdrawn.

Claims 1-20 are under examination.

Claim Objections

Claim 1 recites a therapy, is applicant referring to a method for the treatment of cancer?

Appropriate correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 4, 6, 8, 10, 12, 14, 16, 18 and 20 provides for the use of radiation therapy, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. Radiation therapy does not set forth an active step in practicing the claimed therapy.

Claim Rejections - 35 USC § 103

Claims 1-20 are/stand rejected under 35 USC 103(a) for the reasons of record
which are restated below.

Applicants arguments were carefully considered but were not found persuasive.

Applicant contends that neither of the Li patents reads on vinorelbine. However, the examiner contends that other drugs that are used in combination with Taxol (vinorelbine- reading on the limitations of claims 1-12). See, i.e., for example, '107 & '163 patents, column 3, lines 11-18. Further, the applicant contends that the Li patents do not explicitly teach carboplatin or cisplatin. However, the examiner contends that the '163 and '107 patents disclose that the paclitaxel formed by conjugating the paclitaxel to a polymer such as poly-L-glutamic acid may be combined with a platinum drug (carboplatin or cisplatin- reading on the limitations of claims 13-20) see, i.e., for example, '107 & '163 patents, column 3, lines 13-17. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art." See MPEP 2144.06.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over as being unpatentable over by Li et al (USPN 5,977,163) in view of Li et al (USPN 6,262,107).

The instant invention is drawn to a therapy for the treatment of cancer comprising administering to a patient in need thereof a polymer-taxane conjugate; wherein the the polmer of the polymer -taxane conjugate is poly-1-glutamate and the taxane of said polymer-taxane conjugate is paclitaxel; and one or more of a group comprising chemotherapeutic agents.

Li et al. ('163) teaches compositions of paclitaxel formed by conjugating the paclitaxel to a polmer such as poly-1-glutamic acid, see, i.e., for example, abstract and claims. Li discloses that the present invention may be combined with a platinum drug (carboplatin or cisplatin-reading on the limitations of claims 13-20) see, i.e., for example, , column 3, lines 13-17.. Li discloses methods could be used to make polymer conjugates of other therapeutic agents, contrast agents, and drugs, including other anti-tumor or anti-cancer drugs. Li teaches such combinations are known in the art and such conjugation would be well within the skill of a routine practitioner of the chemical art, and as such would fall within the scope of the claimed invention, see i.e., for example, column 2, line 61- column 3, line 17. Other drugs that are used in combination with Taxol (vinorelbine- reading on the limitations of claims 1-12). See, i.e., for example, '107 & '163 patents, column 3, lines 11-18.

Li et al. ('107) teaches compositions of paclitaxel formed by conjugating the paclitaxel to a polymer such as poly-L-glutamic acid, see, i.e., for example, abstract and claims. Li discloses that the present invention may be combined with a platinum drug (carboplatin or cisplatin-reading on the limitations of claims 13-20) see, i.e., for example, , column 3, lines 13-17. Li discloses methods could be used to make polymer conjugates of other therapeutic agents, contrast agents, and drugs, including other anti-tumor or anti-cancer drugs. Li teaches such combinations are known in the art and such conjugation would be well within the skill of a routine practitioner of the chemical art, and as such would fall within the scope of the claimed invention, see i.e., for example, column 2, line 61- column 3, line 17. Other drugs that are used in combination with Taxol (vinorelbine- reading on the limitations of claims 1-12). See, i.e., for example, '107 & '163 patents, column 3, lines 11-18.

Parimoo et al. (Journal of the National Cancer Institute, 1996, vol. 88, no. 15, pp-1079-1080) discloses severe neurotoxicity from vinorelbine-paclitaxel combinations in patients. See entire article. This points to the need for experimentation to achieve the correct dosage combinations.

Vogel (The Oncologist, 1999, vol. 4, no.1, pp-17-33) discloses combination therapies with taxanes or vinorelbine. Vogel discloses that an exhaustive review of all possible combinations of available drugs is beyond the scope of the current paper, but Vogel does disclose a variety of pharmaceuticals used to treat breast cancer, including the elected species of vinorelbine. See, for example, page 23.

As set forth in *In re Kerkhoven*, 205 USPQ 1069 (CCPA 1980), "It is *prima facie* obvious to combine two compositions each of which is taught by prior art to be useful for same purpose

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in order to form third composition that is to be used for very same purpose; the idea of combining them flows logically from their having been individually taught in prior art.” See MPEP 2144.06.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claim invention because the ‘163 and ‘107 patents disclose that the paclitaxel formed by conjugating the paclitaxel to a polymer such as poly-L-glutamic acid may be combined with a platinum drug (carboplatin or cisplatin- reading on the limitations of claims 13-20)see, i.e., for example, ‘107 & ‘163 patents, column 3, lines 13-17. Other drugs that are used in combination with Taxol (vinorelbine- reading on the limitations of claims 1-12). See, i.e., for example, ‘107 & ‘163 patents, column 3, lines 11-18. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

All claims are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm..


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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8/17/07

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Andrew Kosar
PATENT EXAMINER, ART UNIT 1654